REMARKS

Applicants respectfully request that the foregoing amendments be made prior to examination of the present application. Upon entry of this amendment, claims 1-2, 5-7, 9-10, 13-17, 28 and 71 are amended, claim 3-4, 8, 11-12, 18-27, and 29-70 are canceled, and claims 73-83 are new. Applicants respectfully submit that the application, as filed, provides adequate support for the limitation substantially "enantiomerically pure" (S)-norketamine. See, for example, paragraph [0036] of the application, as published.

Statement of the Substance of the Interview

Applicants' attorney wishes to thank the Examiner for the courtesy of granting a telephonic interview on 29 February 2008. During the interview, the Examiner and Applicants' attorney discussed how best to move the prosecution of the pending application forward, while overcoming the Examiner's rejections of record. The amendment of the pending claims to recite additional limitations that are not taught, disclosed, or suggested by the prior art of record was viewed by the Examiner with favor. Therefore, in an effort to focus the issues, Applicants' have presented an amended set of claims, as well as new claims, which recite such additional limitations along the lines discussed with the Examiner, including the recitation of specific dosage ranges, patient populations, and, more specifically, the avoidance of a specific side effect, dysphoria. Favorably consideration by the Examiner is respectfully solicited. If further discussion is deemed warranted, the Examiner is invited to call the undersigned without hesitation.

Claim Rejections Under 35 U.S.C. § 102

Claims 1-2 were rejected as being allegedly anticipated under 35 U.S.C. § 102(b) by Ebert *et al.*, European Journal of Pharmacology, Aug. 20, 1997, 333 (1):99-104, ("Ebert"). Without acquiescing to the propriety of the Examiner's allegation, claim 1 has now been amended to include limitations recited in previously submitted claims 8 (a dosage range) and 17 (below a level that induces dysphoria). As the Examiner and Applicants' counsel agreed, neither of these additional limitations is taught, disclosed, or suggested by Ebert. Thus it is respectfully submitted that the rejection of claims 1-2 has now been overcome. Favorably

reconsideration of amended claims 1-2 and withdrawal of the rejection are respectfully requested.

Claim Rejections Under 35 U.S.C. § 103

Claims 5-9, 12-18, 21-25, 28-31 and 71 stand rejected under 35 U.S.C. § 103(a) for allegedly being obvious over Ebert *et al.*, European Journal of Pharmacology, Aug. 20, 1997, 333 (1):99-104, ("Ebert") in view of US Patent Application 2005/0148673 ("Harbut"). This rejection is respectfully traversed for the reasons provided below.

Harbut does not remedy the deficiencies of Ebert (as discussed above) to arrive at all the elements of the pending claims, as currently amended. Indeed, aside from not teaching, disclosing, or suggesting all the limitations found in the pending independent claims, Harbut only discloses the direct administration of racemic ketamine, *not* substantially enantiomerically pure (S)-norketamine. As one of ordinary skill in the art would recognize, assuming that both enantiomers of ketamine are metabolized "equally," the administration of *racemic* ketamine will give rise to *racemic* norketamine.[1] The administration of substantially enantiomerically pure (S)-norketamine is yet one more step removed from even the administration of racemic norketamine.

Arguably Harbut *teaches away* from the administration of norketamine directly, let alone substantially enantiomerically pure (S)-norketamine, stating that norketamine is but 25% as effective as ketamine in reducing pain. See Paragraph Nos. [0081] and [0136]. Applicants would also like to emphasize that there is nothing obvious about the self-administration on an outpatient basis of substantially enantiomerically pure (S)-norketamine because of "convenience and ease [of use]" because it was not at all clear, prior to the present invention, that an amount of substantially enantiomerically pure (S)-norketamine can be self-

[1] Applicants note, in addition, that Harbut's preferred route of administration is *intravenous* administration, which gives rise *not at all* to a metabolic product that would normally be associated with first passage of ketamine through a liver. Once administered directly *into the bloodstream*, it is respectfully adduced, upon information and belief, that ketamine is not metabolized, in a traditional sense, into substantial amounts of norketamine – let alone substantially enantiomerically pure (S)-norketamine. Accordingly, there is little, if anything, inherent in the amounts of norketamine, let alone substantially enantiomerically pure (S)-norketamine, which can be expected or predicted from an intravenous administration of racemic ketamine.

administered safely to treat pain without incurring an unacceptably high risk that self-administration will result in dysphoria and/or anesthesia.[2]

Therefore, the proposed combination of Ebert and Harbut does not give rise to a finding of *prima facie* obviousness. Having thus overcome the Examiner's rejection, Applicants respectfully request that the pending claims be favorably reconsidered and that the rejection for alleged obviousness be withdrawn.

Conclusion

Applicants respectfully submit that the present set of claims satisfies all statutory requirements and recites subject matter that is patentable over the disclosures of the prior art of record. A Notice of Allowance is cordially solicited.

The Commissioner is hereby authorized to charge any additional fees which may be required regarding this application under 37 C.F.R. §§ 1.16-1.17, or credit any overpayment, to Deposit Account No. 19-0741. Should no proper payment be enclosed herewith, as by a check or credit card payment form being in the wrong amount, unsigned, post-dated, otherwise improper or informal or even entirely missing, the Commissioner is authorized to charge the unpaid amount to Deposit Account No. 19-0741. If any extensions of time are needed for timely acceptance of papers submitted herewith, Applicant hereby petitions for such extension under 37 C.F.R. § 1.136 and authorizes payment of any such extensions fees to Deposit Account No. 19-0741.

Respectfully submitted,
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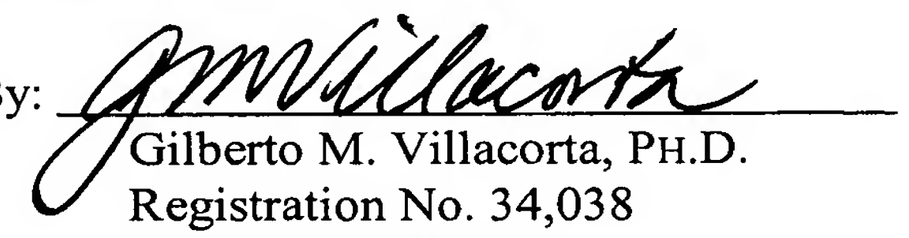
By: 
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[2] To the point, there is no prescription drug product that is approved by the United States Food and Drug Administration, which a patient can self-administer to treat pain and which contains as an active ingredient, ketamine (available only in injectable dosage form) or norketamine (not available at all). Thus, the present invention would provide relief to a host of patients who are in dire need of pain relief, who would not otherwise receive treatment except under costly treatment in a hospital or inpatient setting.